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Official Contact: Mirna DiPano– Director, Quality & Regulatory

Proprietary or Trade Name: Model HEM-7200-Z (BP742)

Common/Usual Name: Noninvasive blood pressure measurement system.

Classification Name/Code: DXN – Noninvasive blood pressure measurement system.

21CFR 870.1130
Class II

Device: Model HEM-7200-Z (BP742)

Predicate Device: Omron – HEM-741CRELN – K052153

Device Description:
The device is an automatic non-invasive blood pressure system. The device is battery powered and can also be powered from an IEC 60601-1 compliant AC adaptor. The device inflates a cuff with an integral pump, then deflates the cuff via an electronically controllable valve. During deflation the cuff pressure is monitored and pulse waveform data is extracted. The extracted pulse waveform data is then analyzed by software which determines pulse rate, as well as systolic and diastolic pressure.

The device is intended to be used with specified Omron cuffs in three sizes to encompass arms ranging from 9 to 17 inches in circumference.

The device also detects the appearance of irregular heartbeats during measurement.

Intended User
Over the counter

Patient Population
This device is intended for use on adults

Indications for Use:
The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population.
The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.

Environment of Use:
Home

Contraindications
There are no known contraindications.

Summary of substantial equivalence

The HEM-7200-Z (BP742) was compared to the predicate HEM-741CRELN (K052153) as in the device comparison table below.
The software algorithm used for determining blood pressure and pulse rate in the HEM-7200-Z (BP742) is identical to that used in the predicate Omron HEM-741CRELN 510(k) K052153.

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Device Comparison

	Omron Hem-7200-Z (BP742) 510(k) not known	Omron HEM-741CRELN 510(k) K052153	Comment
Indications for Use	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population. The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population. The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.	Identical
Patient Population	Adult	Adult	Identical
Environment of Use	Home	Home	Identical
Prescriptive	OTC	OTC	Identical
Patient Connection	Yes via cuff	Yes via cuff	Identical
Technology	Oscillometric	Oscillometric	Identical
Measurement range	Pressure: 0-299mmHg Pulse rate: 40 to 180 bpm	Pressure: 0-299 mmHg Pulse rate: 40 to 180 bpm	Identical
Accuracy or pressure indicator	+/- 3 mmHg or 2% of reading	+/-3 mmHg or 2% of reading	identical
Accuracy Pulse Rate	+/-5%	+/-5%	Identical
Inflation Method	DC rolling pump	DC rolling pump	Identical
Deflation Method	Dynamic linear deflation	Dynamic linear deflation	Identical
Display Type	LCD	LCD	Identical
Irregular pulse detection	Yes	Yes	Identical
Auscultatory	No	No	Identical
Power Source	AA battery or AC adapter	AA battery or AC adapter	Identical
Operating Conditions	Temperature: 10° to 40° C Humidity: 15 to 90% RH	Temperature: 10° to 40° C Humidity: 30 to 85% RH	Similar
Storage Conditions	Temperature: -20° to 60° C Humidity: 10 to 95% RH	Temperature: -20° to 60° C Humidity: 10 to 95% RH	Identical
Dimensions	141 mm (L) × 123 mm (W) × 85 mm (H)	141 mm (L) × 121 mm (W) × 86 mm (H)	Similar
Weight	12 oz	12 3/4 oz	Similar

Differences Between Other Legally Marketed Predicate Devices
The OmronHEM-7200-Z (BP742) is viewed as substantially equivalent to the predicate device because: The HEM-7200-Z (BP742) uses the exact same technology and has substantially equivalent indications for use. The differences that exist between the devices are insignificant in the terms of safety or effectiveness.

Indications –
The indications for use are identical

Prescriptive – The HEM-7200-Z (BP742) and H HEM-741CRELN are both OTC.

Design and Technology – The HEM-7200-Z (BP742) has equivalent design and features as the predicate and has the identical technology to the predicate.

Performance and Specifications – The HEM-7200-Z (BP742) has equivalent specifications of performance as the predicate.

Compliance with standards – The HEM-7200-Z (BP742) and predicate device declare compliance with IEC 60601-1 and IEC 60601-1-2.

Materials –
The patient contact materials of the device (the cuffs) have been cleared in other 510(k) submissions as described in **Section 15 – Biocompatibility**. Materials are detailed in Section 15 as well.

Environment of Use –
The HEM-7200-Z (BP742) and predicate are both intended for home use

Patient Population –
The HEM-7200-Z (BP742) and predicate are both for adult populations

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Performance Testing:

We have performed bench tests and found that the HEM-7200-Z (BP742) met all requirements specifications and standards requirements and were found to be equivalent in comparison to the predicate. Testing includes the following:

- Verification Testing
- Testing for compliance to IEC 60601-1
- Testing for compliance to IEC 60601-1-2
- Testing for compliance to AAMI SP10
- Comparative Testing to the Predicate

Testing to insure clinical accuracy of the device in accordance with ANSI/AAMI/ISO 81060-2. This testing was performed on 85 adults with results showing compliance to the standard.

Conclusion
Omron maintains that the HEM-7200-Z (BP742) is substantially equivalent to the predicate HEM-741CRELN (K052153) in indications for use, patient population, and environment for use, technology characteristics, specifications / performance and compliance with international standards

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 29 2012

Omron Healthcare, Inc.
c/o Paul Dryden
ProMedic, Inc.
24301 Woodsage Drive
Bonita Springs, FL 34134

Re: K121932
Trade/Device Name: HEM-7200-Z (BP742)
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: II (two)
Product Code: DXN
Dated: June 27, 2012
Received: July 2, 2012

Dear Mr. Paul Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: _____ (To be assigned)

Device Name: HEM-7200-Z (BP742)

Indications for Use:
The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population.
The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.

Prescription Use (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use _XX_** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121932